Northern Adelaide Local Health Network

Other Research Projects Submission Guidelines

(NOT CLINICAL TRIALS)

Government of South Australia
Health
Northern Adelaide
Local Health Network

CONTENTS

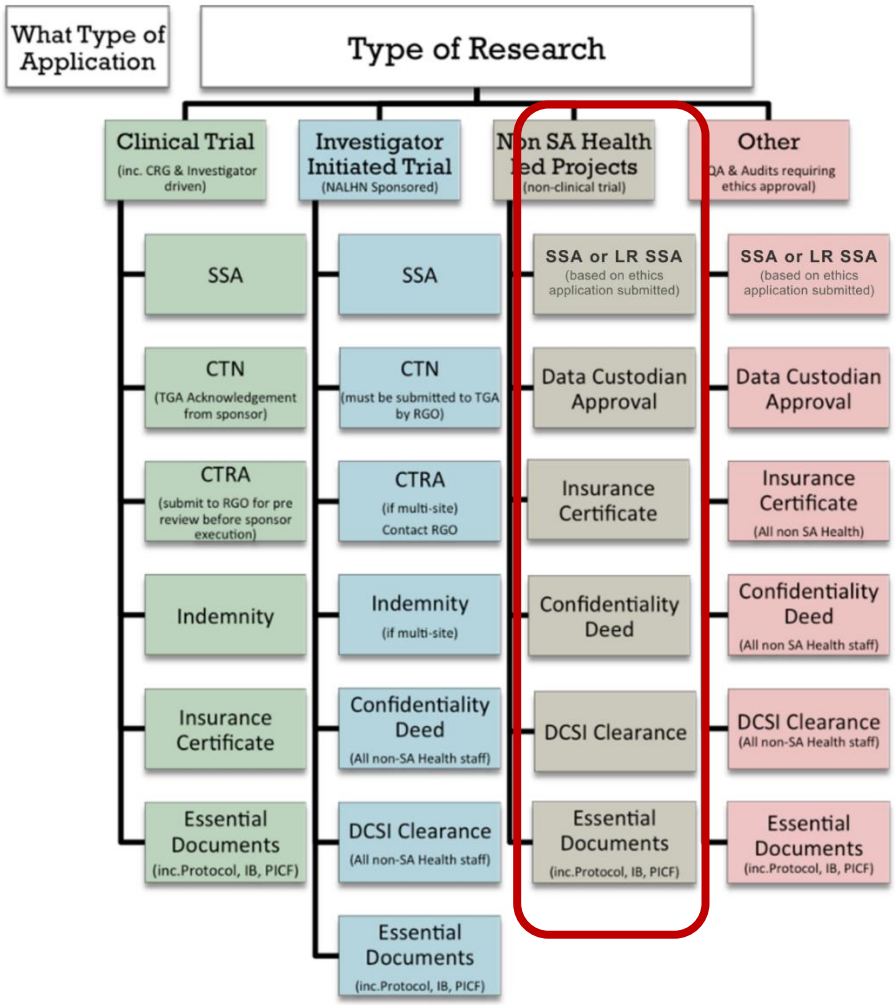
INTRODUCTION

In accordance with the, SA Health Research Ethics and Governance Policy all research within the Northern Adelaide Local Health Network (NALHN) requires authorisation of the delegated officer (Executive Director of Medical Services) before commencing. The Research Governance Office is keen to discuss your project proposals with you at an early stage wherever possible and is here to help navigate the necessary paperwork needed to lodge a research application.

While clinical trials have clearly defined governance guidelines, all research projects irrespective of their level of complexity must be registered with the Research Governance Office. Please refer to the clinical trials guidelines and investigator initiated guidelines for details.

Similarly Quality Assurance and Audits Submission Guidelines projects have specific definitions and rules in their separate guideline.

For all other projects the following guideline will assist researchers in navigating the NALHN research governance process.


What Type of Application
Type of Research
Clinical Trial
(inc. CRG & Investigator driven)
Investigator Initiated Trial
(NALHN Sponsored)
Non SA Health led Projects
(non-clinical trial)
Other
QA & Audits requiring ethics approval)
SSA
CTN
(TGA Acknowledgement from sponsor)
CTRA
(submit to RGO for pre review before sponsor execution)
Indemnity
Insurance Certificate
Essential Documents
(inc.Protocol, IB, PICF)
SSA
CTN
(must be submitted to TGA by RGO)
CTRA
(if multi-site)
Contact RGO
Indemnity
(if multi-site)
Confidentiality Deed
(All non-SA Health staff)
DCSI Clearance
(All non-SA Health staff)
Essential Documents
(inc.Protocol, IB, PICF)
SSA or LR SSA
(based on ethics application submitted)
Data Custodian Approval
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DCSI Clearance
(All non-SA Health staff)
Essential Documents
(inc.Protocol, IB, PICF)

SITE SPECIFIC ASSESSMENTS (SSA)

Research that involves a risk of harm is considered **more** than low risk research. See link to the National Statement on Ethical Conduct in Human Research (2023) paragraphs 5.1.10 to 5.1.18

Site Specific Assessment Form – ***Greater than low risk studies*** are now required to be completed on the Research Governance and Ethics Management System (**GEMS**) website which can be located at, Research GEMS . Please review the user guides for step-by-step instructions on how to navigate the Research GEMS.

GEMS is designed to enable a more consistent and streamlined process for research applicants who wish to conduct research within SA Health.

Research GEMS allows researchers to:

- complete their Human Research Ethics Application and Site-Specific Assessment forms
- monitor approval progress and
- submit post approval monitoring to their local Research Office.

All SA Health sites are now accepting new applications for ethics and site assessments through Research GEMS. All Current studies have been migrated into the system and can be accessed through the Research GEMS web-based platform.

Feel Free to contact the NALHN Research Office for further guidance or support **healthnalhnrgo@sa.gov.au**

Technical Support – GEMS

Please review the user guides for step-by-step instructions on how to navigate the Research GEMS system or contact the NALHN Research Office on phone: 818-29346 or email :**healthnalhnrgo@sa.gov.au** for further guidance or support.

Helpful Hints

Frequently Asked Questions regarding GEMS

Completing the site application part C: Department and Services guide

Dual Submissions

Site assessment and ethical review may occur in parallel. However, the decision to authorise or not authorise the commencement of a research project at the site can only be made once the HREC has approved the project.

Artificial Intelligence (AI) and Large Language Model (LLM) tools

Data Integrity and Accuracy: Using large volumes of algorithms and data poses a risk of biased or discriminatory outputs, and the algorithms that generate these results are often not transparent to most users. It's essential to regularly monitor and assess AI tool usage to ensure they are being applied responsibly, ethically, safely, and in compliance with laws and government policies. Additionally, implement an incident reporting system and investigative process to detect and address any misuse of AI tools.

For all applications using a new AI product, the researchers need to submit an IT Security Assessment for each product, via the – via Digital Health SA–**Information Asset Classification Assessment pathway.** Researchers can find the relevant Information Security policies and email contact for ICT security policies :: SA Health and the Information Asset Classification Assessment form can be found here.

LOW RISK APPLICATIONS

The Low Risk application form is an condensed site -specific assessment that may be used for studies that meet the Low Risk criteria:

The NHMRC National Statement on Ethical Conduct in Human Research (2023) defines low risk as research, including some types of clinical trials, in which the only foreseeable risk is no greater than discomfort. Accordingly, research in which the risk for participants or others is greater than discomfort is not low risk research. Research in this category is considered higher risk research and carries risk of harm. Higher risk research requires review by an HREC

Figure1: Risk profiles of research (from the NHMRC 2023)

Lower risk		**Higher risk** (Individual, group, community, societal or global)	
Minimal	**Low**	**Greater than low**	**High**
No risk of harm or discomfort; potential for minor burden or inconvenience*	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

The National Statemen on Ethical Conduct in Human Research, provides that Institutions are responsible for establishing procedures for the ethical review of human research. That review can be undertaken at various levels, according to the degree of risk involved in the research (see Chapter 2.1: Risk and benefit and Chapter 5.1: Governance responsibilities of institutions). Research with a greater than low level of risk (as defined in Chapter 2.1) must be reviewed by an HREC. Research involving no more than low risk may be reviewed under other processes described in 5.1.10 to 5.1.14. Institutions may also determine that some human research is exempt from ethics review (see 5.1.15 and 5.1.18

Low Risk Application Form is used for expedited ethics and governance review of research studies that are considered low risk according to the National Statement (2023).

Formal determination of whether a study is low risk and/or is eligible for expedited review is made by the Chair of the Ethics Committee upon receipt of an application. Low Risk Studies require both ethical approval from the relevant HREC and governance authorisation to commence at SA Health sites.

There are three types of Low Risk applications: -

1. The Low risk form is available on our NALHN Research web page. If your application has already achieved ethics approval by an National Mutual Accepted HREC please ensure to advise on your application. Refer to the Low Risk Research Protocol Guidelines
2. For studies involving other SA Health or public health sites submission is via GEMS system
3. You already have HREC approval

To assist with the Low Risk expedited process please ensure to provide as much detail as possible: -

e.g. Referral site only, recruiting at the site through the distribution of posters, will there be non- SA Health staff accessing site, provide details of leaflets, handouts, surveys and questionnaires, advising use of data or tissues held at NALHN.

Contact us at healthnalhnrgo@sa.gov.au or (08) 8182 9346 to discuss any queries that you may regarding your project.

INSURANCE

The Principal Investigator (PI) is responsible for confirming the insurance and indemnity arrangement for the research project. The PI must provide all required supporting documentation to the RGO. This generally includes copies of the relevant insurance certificates PLUS an email from the partnering organisation confirming that this study is covered by the insurance.

Any changes to insurance (including annual renewal) must be lodged with the RGO for ratification.

Please be aware that some projects will require Legal Governance and Insurance Services (LGIS) to review and approve insurance, and this can delay the processing of your SSA.

SA Health Employees

SA Health employees conducting a research project in the capacity of their employment with SA Health are covered by SA Health insurance where approval from a SA Health HREC or National Mutual Acceptance (NMA) HREC has been obtained. No further supporting documentation is required.

Dual Employment

If the researcher is an SA Health Employee, but has dual employment with a University or South Australian Health and Medical Research Institute (SAHMRI) or another organisation, or is also a university student, and is conducting a research trial/project in the capacity of their non SA Health employment, or as part of their private studies, indemnity must be provided by the University or SAHMRI and/or third party sponsor.

Non-SA Health Employees

Conducting research at an SA Health organisation that involve SA Health patients, staff, resources or data to support the project, the PI must provide appropriate insurance documentation from the non-SA Health organisation. Appropriate insurance documentation includes current insurance certificate/s and written insurance approval from the organisation. These requirements include research projects conducted by staff and students of academic institutions, such as Universities.

New Data Collection (REDCap)

(Research Electronic Data Capture) REDCap is the NALHN preferred method of building and managing investigator-initiated research data bases and surveys. REDCap, a robust web-based survey and data collection tool, available to NALHN. It is designed to simplify and streamline the process of creating and managing surveys for research studies. quality improvement initiatives. and other data collection projects.

For further information: see link

(Note that NALHN REDCAP is now mandatory for data management of research studies undertaken at NALHN).

Third Party Sponsor

For clinical research TRIALS with third party sponsors it is a requirement that the Sponsor indemnifies the trial and provides evidence of indemnity, by way of Certificate of Currency (this is in addition to SA Health and/or non-SA Health insurance cover).

For research PROJECTS sponsored by a third party, including commercially sponsored clinical trials, the sponsor must supply evidence of its insurance cover. A sponsor's insurance cover must as a minimum identify the local site, investigator and research staff, and participants involved in the research project. For all commercially sponsored clinical trials, the 'Medicines Australia Form of Indemnity for Clinical Trials – Standard' must also be submitted

Budget process

For investigator-initiated projects supported by in-kind support at NALHN, a summary of the project's required resources and hours must be provided. The Divisional Business Consultant and Divisional Director must also approve the summary of the In Kind budget.

NALHN Credentialling

NALHN must ensure all staff, contractors, visiting private practitioners, volunteers and students are credentialed. If any of the investigators listed on the application are working at NALHN in clinical capacity, they must have up-to-date credentialing within NALHN. If the credentialing details are out of date, we will request evidence of renewal and the study will not proceed.

NALHN Credentialling Officer- Telephone 08 82821699 or email
Megan Glowik health.nalhncredentialling@sa.gov.au

ESSENTIAL DOCUMENTS

SSA Fee Form

The NALHN Office for Research charges fees according to the SA Health Research Ethics and Governance Fees Schedule available here. Please see the SA Health Fee Form –SA Health Research Governance Fee Schedule

Within the SA Health fees schedule there are three categories that are covered:

1. Clinical Trials with Full Commercial Sponsorship

2. Non-Commercially Sponsored Clinical Trials / Cooperative Research Group (CRG)

3. Contract Review

To define clinical trials, we acknowledge the following the World Health Organisation definition:

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes

Human Research Ethics Committee (HREC)

NALHN does not have a Human Research Ethics Committee; however, the Research Governance Office will accept any National Mutual Accepted HREC ethics with a Site-Specific Assessment form. NMA Ethics committees can be located on the SA Health website.

Study Protocol

The Study Protocol is an essential document for both the HREC and the RGO.

For Low Risk studies please see the Low Risk Protocol Guideline form for both the HREC and the RGO.

Participant Information Sheets and Consent Forms (PISCF)

NALHN endorses use of the NHMRC standardised PICFs which are designed for three categories of participants identified by the National Statement:

When completing the Master PISCF and Site Specific PISCF please refer to the Participant Information Sheets and Consent Forms fact sheet.

Investigator CVs

Investigators should provide a current copy of their Professional/Academic CV. Please ensure that the CV details relevant research experience, academic qualifications and publications.

GOOD CLINICAL PRACTICE CERTIFICATE

As part of the implementation of the National Clinical Trials Governance Framework and the Therapeutic Goods Administration (TGA) GCP Inspection Audits, investigators will be required to undertake GCP training and subsequent refresher training to meet compliance as mandated by SA Health.

The various Health Networks are working with SA Health towards ensuring that all staff involved in **any clinical research** (not only those involved in the design and conduct of clinical trials) undertake GCP training and hold a current certificate in GCP. This includes principal investigators, associate investigators, trial managers/coordinators and research nurses etc.

To ensure NALHN is compliant with the minimum training requirements, all staff (NALHN, SAHMRI, University etc) involved with undertaking any clinical research at NALHN must undertake GCP training. Evidence of GCP training will be part of the research ethics and research governance approval processes.

Certificates are kept on file in the Research Governance Office, so if you have provided a certificate within the past two years, you do not need to provide it with every new SSA application.

Further information can be found on the Therapeutic Goods Administration website.

- Global Health Network Training Centre
- Syneos Health (formerly INC Research)

Please note: This is interim advice and further information will be provided when available from SA Health

Police Clearances

Non-SA Health staff coming on site as part of a research study must provide a NALHN confidentiality deed and National Police Certificate (NPC) if they are working with adults at NALHN. If the study involves participants under the age of 18, child-related employment screening through the Department of Human Services (DHS) must be provided in place of an NPC. This is to be in compliant with the South Australian Health Criminal and Relevant History Screening Policy Directive available Criminal and Relevant History Screening. There are numerous options for a police check online via accredited agencies. As a way to ensure compliance, screening and confidentiality are standard conditions on our governance authorisation:

- It is the responsibility of the Principal Investigator to ensure any non-SA Health personnel who conducts or monitors research meets SA Health screening requirements as per the SA Health Criminal & Relevant History Screening Policy Directive before they access any SA Health site. The cost of any such screening is the responsibility of the individual accessing the site or their employer. Working with children check

Confidentiality Agreement for non- SA Health Staff

A NALHN confidentiality deed will need to be signed by all non-SA Health staff that will require access to SA Health data.

Radiation Safety Report / Standard of Care Declaration by PI

Any request for a statement certifying no additional radiation exposure must be submitted to the SAMI Radiation Officer through the Redcap Database.

This rigorous process may attract a fee for reviewing however SAMI are happy to waive the fees for locally initiated research on request as appropriate.

Research involving gene technology and related therapies, drugs and/or ionising radiation may require specific notification, registration or licence requirements. Please refer to the SA Health Research Ethics Operational Policy Directive.

All research involving any form of radiation must comply with relevant National and State legislation, organisational policies and procedures, and codes and standards of practice provided by the NHMRC and the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).

Evidence of these requirements (including the HREC approval) should be attached to the SSA to permit the RGO to assess whether the appropriate processes and documents have been completed by the applicant.

Advertising

All advertisements including the SA Health Logo, and all radio/television/press/social media advertising must be first approved by the NALHN Communications Department:

HEALTH.NorthernCommunication@sa.gov.au

Evidence of approval from Media and Communications must be included with your SSA/Low Risk applications.

Corporate Identity Policy
https://www.sahealth.sa.gov.au/wps/wcm/connect/ddbe6580462bc31e8967896dc301fde5/Directive_Corporate%2BIdentity_Nov2014.pdf?MOD=AJPERES&CACHE=NONE&CONTENTCACHE=NONE

Social Media Policy

https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/contact+us/social+media+policy+terms+and+conditions+of+use

SA Health Logos

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Other Contracts and Amendments

It is essential that any third-party agreements be negotiated and presented for signing at the same time as the researcher lodges the SSA.

The NALHN Executive Director of Medical Service / or nominated delegate is the only person authorised to sign contracts on behalf of NALHN. Do not edit the body of the standard agreement. Any non-standard agreements (not on an approved template) will need to be reviewed by a legal representative prior to signing.

These commonly include:

- Collaboration agreements with Universities/Medical Research Institutes/Hospitals
- Funding agreements
- Material Transfer Agreements (MTAs)
- Multi-Institution Agreements (MIAs)
- Intellectual Property Deeds
- Moral Rights declarations
- Service agreements
- Import/Export permits

- Student scholarship agreements
- Sanctioned Country clearances

Researchers should be aware that contract negotiations may take months, so these should be discussed with the NALHN Research Office at the earliest opportunity.

NEXT STEPS

Signing

There are two types of sign off
Low Risk Studies and *Greater than Low Risk Studies* (GEMS-SSA)

1. Before lodging your **Low Risk application**, you must obtain the necessary approvals from all of the various departments, units, divisions pertinent to your study. For further information about delegated signatories please contact the NALHN Research Office email : healthnalhnrgo@sa.gov.au

   Please be aware of the below three step process for Low Risk submissions: -

   1. Send all documents through to the RGO for validity check
   2. The RGO will confirm validity, you will be required to send through to the HREC for Ethics approval
   3. Once the HREC approval has been undertaken it must be provided to the RGO for execution to executive, you will then receive a letter of approval from the RGO to commence your study.

   No study is to commence at the NALHN sites without the NALHN RGO final letter of approval

2. If your application is **Greater than Low Risk** and will be submitted via Research GEMS, please ensure to include the all of the various departments, units, divisions pertinent to your study- Head of Unit, Divisional Director, Business Consultant, etc. If your study is cross divisional, we will also require both divions to note their support. See helpful hint - Completing the site application part C: Department and Services guide

Feel free to contact the Research Secretariat- PH: 08 81829346 or email healthnalhnrgo@sa.gov.au should you have any other queries.

Lodging your application

How to submit your applications: -

- Follow the above **Low Risk pathway** or the **Greater than Low Risk - GEMS** (SSA) submission pathway
- Complete the required steps / forms (for you process to be managed with promptness it helps to ensure your application is provide in complete form)
- Low Risk ,Email the cover sheet, Low Risk application, and ALL supporting documents to healthnalhnrgo@sa.gov.au for validation check (this step is required prior to submitting to the HREC)
- Greater than Low Risk (SSA) – Follow the GEMS system process as listed above.

Hard copies are not required (except for CTRA and Medicines Australia Indemnity forms)

Note that if your submission is being managed via GEMs you will need to ensure that the CTRA and Medicines Australia Indemnity forms are provided to the NALHN Research Office via email healthnalhnrgo@sa.gov.au

NOTE CONTRACTS are not managed via GEMS. *You need to email these to us.* healthnalhnrgo@sa.gov.au

Once submitted, your application is reviewed by the RGO for final authorisation by the CEO/delegate. The project must **not commence until you receive a letter of authorisation from the RGO.**

NALHN supports dual submission of ethics and governance for Greater than low risk applications, (SSA),. While SSAs (Greater than low risk applications) can be submitted at any time before the project commences, dual submission allows the governance and ethical review to occur in parallel. **Your HREC approval is not sufficient to start the study**. A final endorsement letter will be provided for the SSA only where HREC approval is obtained, and the letter provided to the RGO.

Partially completed (unsigned/invalid) applications will be returned to the applicant. If you have not submitted an application within 3 months of receiving ethical approval, the RGO will contact the Principal Investigator for clarification. Please contact the RGO if you anticipate a lengthy delay in submitting an SSA.

CONTACT US

The team at the NALHN Research Office are happy to assist you in navigating the necessary documents and processes outlined in this guide, and to give advice on project-specific information.

Contact us on +61 8 8182 9346 or healthNALHNrgo@sa.gov.au

For more information
NALHN Research Office
(08) 8182 9346
email: healthNALHNRGO@sa.gov.au

sahealth.sa.gov.au/nalhn

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